IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE TRICOR INDIRECT PURCHASER ANTITRUST LITIGATION	)	C.A. No. 05-360 (KAJ) (Consolidated)
THIS DOCUMENT RELATES TO: PACIFICARE HEALTH SYSTEMS, INC. C.A. No. 05-591 (KAJ)	)	**JURY TRIAL DEMANDED**

PLAINTIFF'S FIRST AMENDED COMPLAINT (Public Version)

1. This litigation arises from a series of actions undertaken by Defendants Abbott Laboratories ("Abbott"), Fournier Industrie et Sante and Laboratories Fournier, S.A. (collectively, "Fournier" and collectively with Abbott, "Defendants") to monopolize sales of fenofibrate drug products in violation of the federal and state antitrust laws.

2. Defendants market fenofibrate drug products under the brand-name TriCor®. TriCor® is used to reduce high levels of low-density lipoprotein cholesterol, also known as "bad cholesterol."

3. Defendants unlawfully monopolized and attempted to monopolize the domestic market for fenofibrate drug products by engaging in an overall scheme to prevent generic competitors from entering the market with lower-cost generic equivalents.

4. The components of Defendants' scheme to thwart generic entry include the following:

(a) Defendants obtained Food and Drug Administration ("FDA") approval to market TriCor® in a particular dosage strength and using a particular delivery method (such as capsules or tablets).

(b) When generic manufacturers developed and sought to market a non-infringing lower-cost generic equivalent of the TriCor® product, Defendants engaged in a range of practices that delayed the launch of the generic product.

(c) During the period when generic entry was blocked by Defendants' delay tactics, Defendants charged supra-competitive prices for TriCor®.

(d) When the delay tactics were about to run their course, and market entry by a generic competitor was imminent, Defendants began marketing and selling a slightly different formulation of TriCor® – adjusting the dosage strength, for example, or switching the delivery method from capsules to tablets. The new formulation was the same medicine, used the same active ingredient, and had the same indications as the old formulation.

(e) At the same time, before the generics could reach the market, and while Defendants still had market exclusivity for the old formulation, Defendants took affirmative steps to eliminate market demand for the old formulation and effectively force the entire market to shift to the new formulation.

(f) As a result, by the time generic manufacturers were allowed to enter the market, Defendants had shifted market demand to a new formulation, over which they again exercised market exclusivity. In essence, Defendants used their market power to ensure that they effectively never faced competition from generic products.

5. Defendants' scheme had the purpose and effect of ensuring that a generic company was effectively unable to launch a competing generic product. Just as a generic manufacturer was about to enter the market with its generic alternative, which could and would be substituted by pharmacists as a lower-cost option, Defendants used their market power to shift market demand away from the dosages and formulations in which the generic manufacturers were about to enter the market. Because the generic product was approved for the old formulation, pharmacists could not legally substitute the generic product for the new TriCor® product, even though the products had the same indications.

6. Defendants' conduct unreasonably restrains competition. By implementing their unlawful scheme, Defendants have precluded generic competition and are able to do so indefinitely.

7. As a direct and proximate result of Defendants' conduct, Plaintiff, PacifiCare Health Systems, Inc. ("PacifiCare"), a third-party payor for TriCor®, has been denied the benefits of free and unrestrained competition in the fenofibrate drug market.

8. Specifically, PacifiCare paid higher prices than it would have paid if a generic alternative would have been available. The generic versions would have been priced significantly below TriCor®.

THE PARTIES

9. Plaintiff PacifiCare Health Systems, Inc. is organized under the laws of Delaware. It maintains its headquarters in Cypress, California. PacifiCare is a third-party payor that has paid and continues to pay some or all of the costs of its members' TriCor® purchases.

10. Defendant Abbott Laboratories is a corporation organized under the laws of Illinois, with its principal office located at 100 Abbott Park Road, Abbott Park, Illinois 60064.

11. Defendant Fournier Industrie et Sante and Laboratoires Fournier, S.A., are French corporations having their principal place of business at 42 Rue de Longvie, 21300 Chenove, France.

JURISDICTION AND VENUE

12. This action is brought under Section 16 of the Clayton Act, 15 U.S.C. § 26, for injunctive relief and the costs of suit, including reasonable attorney's fees, for injuries to plaintiff resulting from, inter alia, Defendants' violations of the federal antitrust laws.

13. The Court has jurisdiction over this action pursuant to 28 U.S.C. § § 1331, 1332 and 15 U.S.C. § 26.

14. This Court has supplemental jurisdiction over the state law claims pursuant to 28 U.S.C. § 1367(a).

15. Venue is proper in this judicial district pursuant to 15 U.S.C. § 22 and 28 U.S.C. §391(b) because Defendants are found or transact business in this District, a substantial part of the affected trade or commerce has been carried out in this District, and a substantial part of Defendants' unlawful scheme took place in this District.

INTERSTATE TRADE AND COMMERCE

16. At all relevant times, TriCor® was manufactured by Defendants and was then sold, shipped and transported across state lines to United States customers located outside the state of manufacture. In connection with the purchase and sale of TriCor®, monies, contracts, bills, and other forms of business communications and transactions were transmitted in a continuous and uninterrupted flow across state lines. Various means and devises were used to effectuate Defendants' actions, including the United States mail, interstate travel, interstate telephone commerce, and electronic commerce. Defendants' activities were within the flow of, and have substantially affected, interstate commerce.

THE RELEVANT MARKET

17. The relevant product market is the market for fenofibrate drug products, such as TriCor®, and its generic bioequivalents rated "AB" by the FDA. The relevant geographic market is the United States. Defendants' market share in the relevant market has ranged from approximately 95% to 100%.

THE REGULATORY FRAMEWORK

18. Under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq. (the "Act"), approval by the FDA is required before a company may begin selling a new drug. To obtain approval, a manufacturer files a New Drug Application ("NDA") containing specific data concerning the drug and patient information.

19. Generic drugs are drugs that the FDA has found to be bioequivalent to brand-name drugs and which provide the same therapeutic effects as the brand-name drugs. The FDA assigns the generic drug an "AB" rating when a generic drug meets the necessary requirements such that it is considered to be bioequivalent to the brand name or reference product.

20. Generic drugs are invariably priced below the branded drugs to which they are bioequivalent. The first generic competitor to enter a market typically does so at a price lower than the price of the equivalent brand-name drug and takes a substantial amount of market share away from the brand-name manufacturer. As additional generic competitors come to market, the price of the generic equivalents continues to fall, and their combined market share continues to grow.

21. When a physician writes a prescription for a brand-name drug such as TriCor®, that prescription permits the patient to receive the drug named or its AB-rated generic equivalent. Because generic drugs are so much less expensive than brand-name drugs, AB-rated generic drugs are substituted for the branded version of those drugs. Under state generic drug substitution laws, pharmacists are permitted or required to substitute a generic product for a brand-name product unless the doctor has indicated that the prescription for the brand-name product must be dispensed as written ("DAW"). Only drugs that carry the FDA's AB generic rating may be substituted by a pharmacist for a physician's prescription for a brand-name drug.

22. The price competition engendered by generic drug manufacturers benefits all purchasers of the drug, who are able to buy a bioequivalent chemical substance at a much lower price.

23. Congress enacted the Hatch-Waxman Act in 1984 to establish an abbreviated process to expedite and facilitate the development, approval and marketing of generic drugs. To

effectuate its purpose, the Hatch-Waxman Act permits a generic drug manufacturer to file an "abbreviated" new drug application ("ANDA"), which incorporates by reference the safety and effectiveness data developed and previously submitted to the FDA by the company that manufactured the original brand-name drug.

24. At all times relevant to this lawsuit, the ANDA filer must make one of four certifications to the FDA:

i. that no patent for the pioneer drug has been filed with the FDA (a "Paragraph I Certification");

ii that the patent (or patents) for the pioneer drug has (or have) expired (a "Paragraph II Certification");

iii. that the patent for the pioneer drug will expire on a particular date and the generic company does not seek to market its generic product before that date (a "Paragraph III Certification"); or

iv. that the patent for the pioneer drug is invalid or will not be infringed upon by the proposed generic company's product (a "Paragraph IV Certification").

21 U.S.C. § 355(j)(2)(A)(vii). In the case of a patent that has not yet expired, the ANDA applicant's only certification options are Paragraph III or IV certifications. If the generic manufacturer makes a Paragraph IV Certification, the ANDA applicant must notify the patent owner of the filing and explain why the patent is invalid or will not be infringed.

25. The patent owner, upon receiving a Paragraph IV Certification from an ANDA applicant, has a 45-day statutory period in which to initiate a patent infringement suit against the applicant. See 21 U.S.C. § 355(j)(5)(B)(iii). If no action is initiated within 45 days, FDA approval of the generic product is not delayed by patent issues. However, if a patent infringement suit is brought within the 45-day window, FDA approval of the ANDA is automatically postponed until the earliest of (a) the expiration of the patents; (b) the expiration of

30 months from the day the patent holder received notice of the paragraph IV certification; or (c) a final judicial determination of non-infringement.

26. As a result, at all times relevant to this lawsuit, brand-name drug manufacturers could file a patent infringement lawsuit, regardless of the lawsuit's merits, and automatically block a generic from entering the market for up to 30 months.

FENOFIBRATE AND THE RELEVANT PATENTS

27. Fenofibrate, the active pharmaceutical ingredient in TriCor®, is a chemical used to treat adults with high cholesterol. Fenofibrate reduces high levels of low-density lipoprotein cholesterol ("LDL-C"), also known as bad cholesterol, and triglycerides by promoting the dissolution and elimination of fat particles in the blood. Fenofibrate also increases levels of high-density lipoprotein cholesterol ("HDL-C"), also known as good cholesterol.

28. Fibrates, such as fenofibrate, are cholesterol-lowering drugs. Other categories of cholesterol-lowering drugs include statins, bile acid sequestrants, and niacin. Each category of cholesterol lowering drug reduces cholesterol differently, has different side-effects, has different drug interactions, and is prescribed for different types of patients. A cholesterol-lowering drug from one category is not interchangeable with a cholesterol-lowering drug from another category.

29. Various fibrate drugs exist, including TriCor® (fenofibrate), Atromid (clofibrate), and Lopid (gemfibrozil). Each fibrate drug is approved by the FDA for different indications, has different side effects, and is prescribed for different types of patients and for people with particular medical histories and ailments. These three types of fibrate drugs are not reasonably interchangeable because of the wide variations in side effects, differences in their approved

indications, differences in how they are ingested, and other differences, including those related to their prescription and efficacy profiles.

30. On January 23, 1990, the United States Patent and Trademark Office ("PTO") issued U.S. Patent No. 4,895,726 ("the '726 patent") to Fournier.

31. The '726 patent claimed a novel dosage form of fenofibrate, which involves co-micronizing fenofibrate with a solid surfactant. The composition was presented in the form of gelatin capsules. In 1997, Fournier granted Abbott an exclusive licence to the '726 patent in the United States.

32. Fournier is also the owner of at least four additional patents involving fenofibrate compositions: U.S. Patent Nos. 6,074,670 ("the '670 Patent"), 6,277,405 ("the '405 Patent"), 6,589,552 ("the '552 Patent"), and 6,652,881 ("the '881 Patent"). The '670 patent was issued on June 13, 2000; the '405 patent was issued on August 21, 2001; the '552 patent was issued on July 8, 2003; and the '881 patent was issued on November 25, 2003. These four patents are collectively referred to below as the "Stamm Patents," after one of their named inventors, Andre Stamm.

33. Each of the Stamm patents claimed methods of preparing a fenofibrate composition to achieve high "bio-availability" (i.e. the rate at which the active medication is delivered or made available to the body).

THE "SUE-AND-SWITCH" SCHEME

The First "Sue-and-Switch": The Illinois Patent Litigation and Defendants' Switch from Capsule to Tablet.

34. On June 20, 1997, Abbott submitted an NDA for a 67mg fenofibrate capsule, which was approved by the FDA on February 9, 1998. Abbott also submitted separate NDAs for 134mg and 200mg fenofibrate capsule, which were approved on June 30, 1999. These products

came to market shortly after receiving FDA approval and were marketed by Abbott under the brand name TriCor®.

35. On December 14, 1999, Novopharm Limited ("Novopharm"), which was subsequently acquired by Teva Pharmaceuticals ("Teva"), filed an ANDA seeking the FDA's approval to market a 67mg generic micronized formulation of fenofibrate prior to the expiration of the '726 patent. Novopharm amended its ANDA, on March 31, 2000 to request approval to market a 200mg capsule, and did so again on November 27, 2000 to request approval to market a 134mg capsule. Along with its ANDAs, Novopharm certified that its proposed fenofibrate formulations did not infringe the '726 patent.

36. On May 9, 2000, Impax Laboratories ("Impax") filed an ANDA seeking the FDA's approval to market a generic micronized fenofibrate capsule in 67mg, 134mg, and 200mg dosages. Impax certified that its formulations did not infringe the '726 patent.

The First "Sue": The Illinois Patent Litigation

37. On April 7, 2000, August 18, 2000, and March 29, 2001, Defendants filed patent infringement actions in the United States District Court for the Northern District of Illinois against Novopharm (which was acquired by Teva in April 2000), Teva, and Impax. The Defendants' lawsuits alleged that the generic manufacturers infringed the '726 patent.

38. Pursuant to the Hatch-Waxman Act, each lawsuit imposed a stay preventing the FDA from granting Teva or Impax final approval to market a generic fenofibrate capsule for up to 30 months from the date Abbott received notice of the ANDA. Under the Hatch-Waxman Act, the FDA was unable to give final approval to any of the generic manufacturers' ANDAs until the 30-month stay had expired or until the patent litigation was resolved.

39. On March 19, 2002, the court granted Teva's Motion for Summary Judgment of non-infringement of the '726 patent. After construing certain claims of the '726 patent, the court held that even with the evidence viewed in the light most favorable to Abbott and Fournier, Teva's proposed generic did not infringe the '726 patent.

40. On April 9, 2002, after the court's opinion holding that Teva's generic did not infringe the '726 patent, the FDA granted Teva final approval to market its 134mg and 200mg fenofibrate capsules. Teva came to market shortly thereafter. Because of a change in FDA regulations regarding the Hatch-Waxman Act, Teva received only tentative approval to market the 67mg capsule until the expiration of Abbott's time to appeal the decision, or a determination by the Federal Circuit upholding the finding of non-infringement.

41. A unanimous panel of the Federal Circuit affirmed the district court's decision on March 20, 2003. Thereafter, Teva received final approval to market its 67mg fenofibrate capsule. As a result of Abbott's lawsuit and appeal, Teva was unable to launch its 67mg capsule until late 2003.

42. On March 26, 2003, the court granted Impax's Motion for Summary Judgment of non-infringement. The FDA subsequently granted Impax final approval to market its fenofibrate capsule on October 28, 2003.

The First "Switch": Capsule to Tablet

43. By filing patent infringement lawsuits, Defendants prevented the FDA from granting final approval to Teva and Impax's generic products for up to 30 months, regardless of the merit of Defendants' patent infringement suits.

44. Moreover, Defendants used the 30-month stay imposed by the Hatch-Waxman Act to ensure that a generic manufacturer would be unable to come to market when the stay

expired. While the stay was still in place, Defendants deliberately eliminated market demand for TriCor® capsules and converted the market to TriCor® tablets.

45. By taking affirmative steps to eliminate demand for the capsules, Defendants ensured that the generic manufacturers would remain unable to compete in the fenofibrate market once their generic capsule products were held to be non-infringing.

46. On November 10, 1999, Abbott had filed an NDA for a TriCor® tablet in 54mg and 160mg strengths. The FDA approved this ANDA on September 5, 2001.

47. Defendants' NDA for TriCor® tablets offered no marketable improvements or benefits to consumers over the TriCor® capsules already on the market. The TriCor® tablets contained the same drug as the earlier-approved capsules, and Defendants even relied upon the same clinical studies to support the NDA for TriCor® tablets that they had used to support the NDA for TriCor® capsules.

48. Although the tablets did not offer any additional health benefits, the introduction of the new tablets enabled the Defendants to prolong their monopoly in the fenofibrate market. Since the TriCor® tablets were technically "new," there were no pending ANDAs seeking approval to market a generic tablet. If an ANDA was filed for a generic TriCor® tablet, Defendants could secure up to an additional 30 months of market exclusivity in fenofibrate tablets by filing another round of lawsuits.

49. With the stay from the Illinois patent litigation still in place, Defendants took advantage of their remaining market exclusivity in fenofibrate capsules to shift the market to fenofibrate tablets. Before the Illinois court had ruled, and before Teva and Impax could receive approvals to market their generic fenofibrate capsules, Abbott abruptly stopped selling TriCor® capsules, removed them from the market, and instructed its sales force to stop detailing and

marketing them. Abbott even destroyed part of its existing inventory of TriCor® capsules rather than selling them.

50. Abbott instead began to sell and market only TriCor® tablets. Abbott's sales force began a concerted effort to ensure that doctors stopped prescribing the capsule formulation and switched over to the tablet formulation.

51. In connection with these efforts, Defendants also removed (or reclassified as "obsolete") the TriCor® capsule code from the National Drug Data File® ("NDDF"), a widely accepted database of available drugs that includes drug descriptions, pricing information, and indications. In so doing, TriCor®'s branded drug code reference no longer existed for purposes of generic substitution laws. Together with Abbott's removal of capsules from the market, this de-listing would ensure that no brand-name reference would exist for the generic capsule product when it came to market. The result would be to prevent a generic fenofibrate capsule from being substituted for the brand-name drug, contrary to the purposes embodied in the regulatory framework of the Hatch-Waxman Act. Defendants removed the capsule code from the NDDF specifically to foreclose generic competition in the fenofibrate product market.

52. The expense of developing TriCor® tablets, switching the manufacturing process to tablets, training a sales force to market the new tablets, convincing doctors to prescribe the new tablets, and eliminating the demand for TriCor® capsules was extraordinary considering that the end result produced a drug with no significant improvements over the drug already on the market.

53. The purpose and effect of Defendants' overall scheme was to prevent generic competition that otherwise would have lawfully existed for fenofibrate capsules. Not only did Defendants delay generic manufacturers from entering the fenofibrate market, but they took

affirmative steps to ensure that the generic fenofibrate capsules would be unable to compete when they did come to market – because the market for fenofibrate capsules would no longer exist.

54. Defendants' anti-competitive scheme worked. Defendants' conduct effectively prevented the generic manufacturers from being able to compete in the fenofibrate market as envisioned under the Hatch-Waxman Act. When Teva launched its fenofibrate capsule, it only captured 5% of the market, whereas a generic usually captures 40% to 80% of the market. The reason was that Teva's generic capsule could not be dispensed as a generic equivalent for the branded product, the TriCor® tablet, and Defendants had used their market power to eliminate the market for the capsule form.

55. As a direct and proximate result of Defendants' scheme to monopolize, Defendants effectively destroyed generic competition that should have begun in 2001 and improperly maintained at least a 95% share of the market for fenofibrate products that would have eroded substantially in the face of competition.

The Second "Sue-and-Switch": The Delaware Patent Litigation and Defendants' Switch from 54mg/160mg to 48mg/145mg

56. Having successfully prolonged their monopoly profits once, Defendants employed the same scheme a second time. Following Defendants' conversion of the fenofibrate market from capsules to tablets, the generic manufacturers filed ANDAs for 54mg and 160mg tablets.

57. On June 17, 2002, Teva filed an ANDA with the FDA for its generic fenofibrate 54mg and 160mg tablets. Teva also certified that its ANDA did not infringe the '726 patent, as well as two additional patents that, by that time, Defendants had listed in the Orange Book: the '670 Patent and the '405 Patent. Teva subsequently amended its ANDA, on July 29, 2003 and

again on December 17, 2003, by filing two additional certifications, one for the '522 patent, and one for the '881 patent, after Abbott listed each of these patents in the Orange Book as applying to TriCor®.

58. In December 2002, Impax filed an ANDA with the FDA for 54mg and 160mg fenofibrate tablets. Impax also certified that its product did not infringe the '726, the '670, and the '405 patents.

The Second "Sue": The Delaware Patent Litigation

59. In response to Teva's ANDA for fenofibrate tablets, Defendants filed three separate patent infringement actions against Teva in the United States District Court for the District of Delaware alleging infringement of five patents. Defendants filed the first action (Civil Action No. 02-1512) on October 4, 2002, alleging that Teva had infringed the '726 Patent, the '670 Patent, and the '405 Patent. Defendants filed the second action (Civil Action No. 03-847) on August 29, 2003, alleging that Teva had infringed the '552 Patent. Defendants filed the third action (Civil Action No. 04-0047) on January 22, 2004, alleging that Teva had infringed the '881 Patent.

60. The first two of these patent infringement actions against Teva once again triggered automatic 30-month stays preventing the FDA from granting final approval to Teva's tablet ANDA for up to 30 months, regardless of the merits of Defendants' lawsuits. Because of legislative reforms to the Hatch-Waxman Act that became effective in December 2003, Defendants were not entitled to a third 30-month stay for filing the third complaint.

61. In response to Impax's ANDA, Defendants filed a patent infringement lawsuit against Impax on January 23, 2003. The filing of the lawsuit triggered the automatic 30-month stay prohibiting the FDA from giving Impax final approval to market a generic fenofibrate tablet.

The issuance and Orange Book listing of the '552 patent and the '881 patent resulted in Defendants filing additional patent infringement complaints against Impax, the first of which triggered an additional 30-month stay.

62. Each of these lawsuits against Teva and Impax in the United States District Court for the District of Delaware were objectively baseless and without merit. They were filed by Defendants for the sole purpose of triggering the statutory 30-month stay and extending the time during which they enjoyed complete exclusivity in the domestic market for fenofibrate drug products. As such, Defendants' conduct in filing these lawsuits is actionable as sham litigation under state and federal antitrust laws.

63. Defendants' lawsuits were without merit because, among other reasons, Defendants knew that the Stamm Patents that they had alleged to be infringed were unenforceable and fraudulently procured, as set forth in greater detail in paragraphs 79-179 below. Because Defendants knew their patents to be unenforceable and fraudulently procured, Defendants had no proper basis either for listing the patents in the Orange Book, or for filing or maintaining any action against Teva and Impax for infringement of the Stamm Patents.

64. Defendants further knew that, independent of the unenforceability of the Stamm Patents, no reasonable basis existed upon which to bring actions for patent infringement against Teva and Impax. Teva and Impax's ANDAs did not infringe the patents in suit, for the same reasons already identified by the District Court for the Northern District of Illinois, and later by the Federal Circuit, in the Illinois patent litigation.

65. On March 5, 2004, the FDA granted tentative approval to Teva and Impax's tablet ANDAs. By granting tentative approval, the FDA confirmed that the generic manufacturers' fenofibrate 54mg and 160mg tablets were bioequivlant to TriCor® tablets of the same dosage

strengths. The tentative approvals by the FDA would have been final approvals but for the successive 30-month stays resulting from Defendants' filing and maintenance of their lawsuits against Teva and Impax.

66. On May 6, 2005, the District Court of Delaware granted Teva's motion for summary judgment of non-infringement of the '670 patent, the '552 patent, and the '405 patent. After construing the patent claims, the Court concluded, as had the Illinois court, that the generic product did not infringe the terms of Defendants' patents.

67. As a result of the summary judgment decision, the FDA granted final approval to Teva's tablet ANDA on May 13, 2005.

68. Shortly thereafter, and after having obtained the delay they sought, Defendants voluntarily dismissed their patent infringement claims. As they had done during the Illinois patent litigation, Defendants again switched the demand for TriCor® while the 30-month stay was in place. Defendants knew that if the market were switched, even with the dismissal of the lawsuit, and even with Teva and Impax obtaining final approval of their generic products, no generic would actually be able to compete.

The Second "Switch": TriCor® 54mg/160mg to TriCor® 48mg/145mg

69. On October 29, 2003, while the Delaware patent litigation was ongoing and the 30-month stay prevented the generic manufacturers from entering the market, Abbott had filed an NDA for TriCor® tablets in 48mg and 145mg dosage strengths.

70. On November 5, 2004, the FDA approved Abbott's new 48mg and 145mg TriCor® tablets. The new tablets were indicated for essentially the same uses as the 54mg and 160mg tablet dosage forms. As with the previous market switch from capsules to tablets, the

new 48mg and 145mg tablets contained the same drug as the 54mg and 160mg tablets. They offered no genuine marketable improvements or benefits to the vast majority of consumers.

71. Before the Court had ruled on the parties' summary judgment motions – which Defendants knew would spell the end of their market exclusivity for the 54mg and 160mg tablets – and before Teva and Impax could receive final approval from the FDA to market their generic 54mg and 160mg tablets, Abbott abruptly stopped selling 54mg and 160mg TriCor® tablets, removed them from the market, and instructed its sales force to stop detailing and marketing them.

72. Abbott instead began to sell and market TriCor® tablets only in the new 48mg and 145mg dosage strengths. Abbott's sales force began a concerted effort to ensure that doctors stopped prescribing the 54mg and 160mg dosage strengths and switched to the 48mg and 145mg versions. Indeed, in promotional material for the new dosages, Abbott's website asked:

> Q: Do I have to switch to the new 145-mg or 48-mg tablets?
>
> A: Yes. The 160-mg and 54-mg tablets will no longer be available.

See http://www.TriCor®tablets.com/consumer/patient_ga/index.htm (visited on May 22, 2005. This sentence has since been deleted from Abbott's website).

73. Further, just as they had done in the switch from capsules to tablets, Defendants once again removed (or reclassified as "obsolete") the TriCor® 160mg and 54mg reference code from the NDDF. In fact, Defendants removed the code on or about May 6, 2005. This was the very day that the Court had granted Teva's motion for summary judgment of non-infringement of the '670 patent, the '552 patent, and the '405 patent, and just one week before the FDA was to grant final approval to the generics' ANDAs.

74. Together with Abbott's removal of the 160mg and 54mg tablets from the market, this de-listing would ensure that no brand-name reference would exist for the generic product, which would in turn, prevent a generic fenofibrate tablet from being substituted for the brand-name drug. Defendants removed the capsule code from the NDDF specifically in order to foreclose generic competition in the fenofibrate product market.

75. Defendants' scheme ensured that new prescriptions would cease being written for the 54mg and 160mg fenofibrate tablet formulations. As a result, pharmacists would not be presented with prescriptions that would allow substitution with a generic version of the 54mg and 160mg tablet formulations, despite the fact that the generic drugs were much less expensive than the brand-name drug.

76. The expense of developing the different dosage strengths of TriCor® tablets, switching the manufacturing process to the new tablets, training a sales force to market the new tablets, convincing doctors to prescribe the new tablets, and eliminating the demand for the old tablets was, again, extraordinary considering that the end result produced a drug with no significant improvements over the drug already on the market.

77. The purpose and effect of Defendants' overall scheme was to prevent generic competition that otherwise would have lawfully existed for fenofibrate drug products. Defendants not only twice delayed generic manufacturers from entering the fenofibrate market, but also twice embarked on a strategy to ensure that the market would be switched – and that the market for the old formulations would be effectively eliminated by the time the generics could finally come to market.

78. Had Defendants not instituted their now-voluntarily-dismissed patent infringement lawsuits, the generic manufacturers would have been able to compete and capture a

significant portion of the market, even if Defendants did subsequently change their formulation. But bringing suit and imposing the statutory stay gave Defendants the time they needed to switch the market and continue to block the generic manufacturers from competing.

WRONGFUL CONDUCT IN THE PROSECUTION OF THE STAMM PATENTS IN THE PTO[1]

79. Fournier committed inequitable conduct before the PTO in the prosecution of all four of the Stamm Patents. As a result, all four of the Stamm Patents are unenforceable.

80. Fournier prosecuted each of the Stamm Patents in the PTO. In addition, Fournier communicated with Abbott concerning the prosecution of the Stamm Patents in the PTO. By way of example, Abbott's and Fournier's privilege log in the Tablet Lawsuits lists several written communications between Abbott and Fournier "regarding 670 patent application." [sic]

81. At all times relevant to this action, Fournier was aware of its inequitable conduct concerning the Stamm Patents. At all times relevant to this action, Abbott was aware of Fournier's inequitable conduct concerning the Stamm Patents.

82. Fournier is the owner of the application that led to all four of the Stamm patents in suit ("the Stamm Patents"). These are U.S. Patent Nos. 6,074,670 ("the '670 Patent"), 6,277,405 ("the '405 Patent"), 6,589,552 ("the '552 Patent"), and 6,652,881 ("the '881 patent"). Fournier's ownership of these applications is by virtue of an assignment of the original patent application for the Stamm Patents recorded in the U.S. Patent and Trademark Office on June 17, 1998, at Reel 9260, Frame 0797. Following that assignment, Fournier filed and prosecuted the applications for all four Stamm Patents at the PTO.

[1] Plaintiff's allegations in Paragraphs 79-179 below track the allegations made by Teva Pharmaceuticals, USA, Inc. in Paragraphs 105-205 of its Second Amended Answer, Affirmative Defenses, and Counterclaims, filed on July 29, 2005. Because PacifiCare's allegations in this section are substantively identical to Teva's, for the sake of uniformity and the convenience of all parties, PacifiCare has not altered the language used in Teva's allegations except where necessary to clarify that the allegations relate to PacifiCare.

83. The Stamm Patents have substantively identical specifications, which relate to particular fenofibrate compositions. Fenofibrate is poorly soluble in water. According to each of the Stamm Patents, the poor hydrosolubility of fenofibrate causes its bioavailability to be "incomplete." *See, e.g.*, the '881 Patent at col. 1, lines 36-44.

84. U.S. Patent No. 4,985,726 ("Curtet"), also owned by Fournier, describes a prior art fenofibrate formulation. Curtet and its European counterpart disclose a method of improving fenofibrate solubility, and thus bioavailability, by co-micronizing fenofibrate with a solid surfactant. *E.g.*, the '881 Patent at col. 1, line 54 – col. 2, line 5.

85. According to each of the Stamm Patents, the dissolution and bioavailability of compositions in accordance with Curtet are "incomplete." *E.g., id.* at col. 2, lines 14-21. The Stamm Patents assert that there is a "need to improve fenofibrate bioavailability" by achieving a dissolution "close to 100% over very short periods of time . . . ." *E.g., id.* at col. 2, lines 22-24.

86. The Stamm Patents define the requirements for dissolution as greater than "10% in 5 minutes, 20% in 10 minutes, 50% in 20 minutes and 75% in 30 minutes in a medium comprised of 1200 ml water to which 2% Polysorbate 80 is added, or of 1000 ml of water to which 0.025 M sodium lauryl sulfate is added, with a blade rotation speed of 75 rpm." *E.g., id.* at lines 25-30.

87. Each of the Stamm Patents asserts that these dissolution requirements are met "by a new method of preparing a pharmaceutical composition by spraying a suspension of the active ingredient onto an inert hydrosoluble carrier." *E.g., id.* at lines 34-37. The Stamm Patents assert that the dissolution requirements were not met by the prior art. For example, the specification of each of the Stamm Patents asserts that "the preparation method in that patent [the Curtet patent]

is not completely satisfactory inasmuch as it does not lead to complete bioavailability of the active ingredient, and suffers from several disadvantages." *E.g., id.* at lines 14-18.

88. Dissolution information is described in Example 2 of each of the Stamm Patents. *See, e.g., id.* at col. 8, line 39 – col. 9, line 37. The specification for each of the Stamm Patents presents dissolution profiles comparing 100 mg tablets of the alleged invention prepared in accordance with Example 1 (*e.g., id.* at col. 8, lines 65-67), with the prior art composition of Lipanthyl 200M, which is "in line with the teachings of [Curtet]" (*e.g., id.* at col. 9, lines 1-7). The dissolution medium was 1200 ml of water having Polysorbate 80. Samples were taken every 2.5 minutes. The results are provided in Figures 1 and 2 of each of the Stamm Patents.

89. Regarding the results of Example 2, each of the Stamm Patents argue: "These results clearly show that the compositions according to the invention have a dissolution profile which is distinctly better than that of the prior art compositions." *E.g.*, Ex. 25, col. 9, lines 12-14. This was an argument for patentability of the claimed inventions of each of the Stamm Patents. This statement was materially misleading as to each of the Stamm Patents because it was based on a comparison between dissolution profiles of the compositions claimed in the Stamm Patents and dissolution profiles for a particular embodiment of the prior art Curtet formulation (Lipanthyl® 200M), when Fournier also had other undisclosed data showing better dissolution results for the same prior art formulation, embodying the Curtet invention, before the first Stamm patent application was filed in the U.S. Indeed, Fournier's undisclosed data showed dissolution profiles just as good as the results claimed in the actual claims of the Stamm Patents. Fournier had this undisclosed data.

90. Thus, the applications for all four Stamm Patents contained assertions – comparing dissolution results to those under the prior art – which were inconsistent with data

Fournier had but did not disclose to the PTO. The undisclosed data included 1997 dissolution test results for an embodiment of Curtet, as well as dissolution results for a commercialized fenofibrate capsule, also prepared according to Curtet. The undisclosed data was highly material because first, it showed that Fournier was presenting a false and misleading argument that Stamm offered a significantly better dissolution profile in comparison to the prior art, and second because it contradicted Fournier's essential argument for patentability as described in the specification of each of the Stamm Patents.

REDACTED

REDACTED

97. Fournier documents containing such data were provided to Abbott.

98. Fournier relied on the misleading dissolution profile comparisons set forth in Example 2, and continued to withhold the material data showing much better dissolution profiles for embodiments of Curtet, throughout the prosecution of the Stamm Patents to overcome rejections based on Curtet and other prior art. At no time did Fournier disclose the data that was less favorable to, and indeed contradicted, its argument for patentability of the Stamm invention over the prior art.

99. During the prosecution of the application that led to the '670 Patent (the first application from the Stamm patent family prosecuted in the U.S.), the Examiner rejected the pending claims as anticipated and/or obvious over Curtet and another prior art reference, Temeljotov. Fournier relied on the misleading Examples and Figures in the specification of the '670 patent to differentiate the claimed subject matter from Curtet. Further, Fournier asserted that the teachings of Temeljotov and another prior art reference, Debouch, have dissolution profiles similar to or less beneficial than the profile for Curtet Lipanthyl® 200M, which had been shown in the Stamm specifications to be inferior to the dissolution profile achieved by the Stamm invention. Thus, Fournier distinguished other prior art based on a comparison to the misleading dissolution data contained in the specification.

100. Fournier repeatedly relied on the misleading dissolution profiles reported in the specification in support of its arguments for patentability of the claims of the '670 patent.

101. Fournier made similar arguments during the prosecution of the application that led to the '405 patent in suit. There, the Examiner rejected Claims 20, 24 and 35 as being anticipated by Temeljotov, and issued a rejection of the pending claims under 25 U.S.C. § 103 as being unpatentable over the combined teachings of Temeljotov, Curtet and Deboeck.

102. In response to the rejections based on Temeljotov, Fournier amended the sole independent claim of the '405 patent to recite that the composition included micronized fenofibrate instead of merely fenofibrate and argued the patentability of the amended claims on the ground that the dissolution rates of "the presently claimed invention" are not the same as, and do not overlap with, the dissolution rates described by Temeljotov. Fournier also attempted to distinguish Temeljotov's composition over the claimed invention by arguing that the dissolution curve of the claimed invention is superior to the dissolution curve of the Temeljotov formulation.

103. Specifically, Fournier argued:

> Applicants respectfully submit that Temeljotov's formulation exhibits, at most, a bioavailability similar to that of Lipanthyl® 200M (as shown in Curtet and Example 2 in the present specification). Thus, the dissolution curve of Temeljotov, if introduced in Figure 1 of the present specification, would be <u>below</u> the curve of Lipanthyl® 200M.
>
> Applicants have also shown (*see* Example 2 of the application) that the presently claimed invention is unexpectedly superior to the Lipanthyl® 200M formulation. Thus, the presently claimed invention is also unexpectedly superior to Temellotov's formulation.
>
> Applicants respectfully submit that the bioavailability results and the dissolution profile experiments confirm the unexpectedly superior properties of the present invention over the disclosure of Temeljotov (and Curtet).
>
> In view of the above, Applicants respectfully submit that Temeljotov does not disclose or suggest the presently claimed invention, and respectfully request that the rejections under §§ 102(b) and 103 be withdrawn

104. In response to the rejection asserting that the invention was obvious over Temeljotov, Curtet and Deboeck, Fournier presented again the arguments against Temeljotov and further argued against Deboeck and Curtet. Fournier argued that:

> the comparative bioavailability was assayed using the composition from Deboeck's Example 2 and Lipanthyl® 200M (column 8, Table 4) . . . Lipanthyl® 200M corresponds to Curtet and has been tested as a comparative example in Example 2 of the present application. The results from this analysis show that the fenofibrate compositions in Deboeck and Curtet exhibit very similar pharmacokinetic parameters (AUC, C_{max} and T_{max}). Since Curtet's Lipanthyl® 200M has reduced bioavailability (i.e., distinct dissolution profile) with respect to the present invention, Applicants respectfully submit that Deboeck's fenofibrate compositions also have reduced bioavailability compared to the present invention, since Deboeck's dissolution profile is similar to that for Curtet's Lipanthyl® 200M.

105. Fournier asserted that "the improved dissolution profile of the presently claimed invention is clearly not disclosed or suggested by Temeljotov, Deboeck or Curtet. The present invention allows for a decrease in the amount of fenofibrate in the formulation, while still achieving the same physiological benefits."

106. Thereafter, during an interview, the examiner proposed incorporating the hydrosoluble carrier into claim 20, to clearly define the composition: "Specifically, the composition must comprise the micronized fenofibrate and a hydrosoluble carrier to give the claimed dissolution profile. Without the hydrosoluble carrier (*i.e.*, drug alone), the dissolution profile would be different." Fournier's representative agreed to the amendment and the claims, as narrowed, were allowed.

107. Fournier continued to mislead the Examiner during the prosecution of the application that led to the '881 patent, after the Examiner rejected prosecution claims 1-14 and 22-41 as obvious over Curtet by itself, in a February 26, 2003 Office Action, at p. 6, Fournier again distinguished Curtet by its dissolution profile. *E.g.*

> Applicants have shown in Example 2 of the application that the presently claimed invention has an unexpectedly superior dissolution profile compared to Lipanthyl® 200M (i.e., teachings in Curtet). Example 2 and Figure 1 in the application demonstrate that the claimed composition has an unexpectedly superior dissolution profile when compared to Lipanthyl® 200M as described by Curtet (and the corresponding EP 330532).

June 25, 2003 Request for Reconsideration, p. 5.

108. The Examiner allowed the claims. The Examiner's Statement of Reasons for Allowance States in part as follows:

> The prior art fail to teach the instantly claimed composition having a dissolution of at least 10% in 5 minutes, 20% in 10 minutes, 50% in 20 minutes and 75% in 30 minutes . . .. The instant invention, as seen in Example 2, has an unexpectedly superior dissolution profile compared to Lipanthyl® 200M (as taught by Curtet). Curtet does not disclose, nor provide motivation to achieve the instant dissolution profile.

August 11, 2003 Notice of Allowance, pp. 2-3.

109. Thus, Fournier relied on the dissolution profile of "Lipanthyl® 200M (i.e., the teachings in Curtet): to distinguish the claimed compositions of the Stamm Patents from Curtet and other prior art.

REDACTED

110. During the prosecution of each of the Stamm Patents, individuals who were substantively involved in the prosecution of the Stamm Patents were aware of data that contradicted the dissolution profile argument relied on throughout the prosecution of the Stamm Patents, were aware of its materiality, and withheld the data because it undermined Fournier's argument for patentability.

111. Philippe Reginault is a named inventor of the Curtet patent.

112. Reginault was employed by Fournier during the pendency of the applications for all of the Stamm Patents. Reginault served as Fournier's director of pharmaceutical development in charge of *inter alia*, formulation, scale up, and analytical development during 1988-2002. Beginning in 2002, Reginault served as Fournier's director of pharmaceutical technologies evaluation.

113. Reginault was involved in the fenofibrate tablet project from a time just after Fournier's initial contact with co-inventor Andre Stamm regarding PharmaPass's fenofibrate formulation, and his involvement continued through at least Abbott's submission of its New Drug Application and the initiation of the patent lawsuits. Reginault was substantively involved in the prosecution of the Stamm Patents during this same time period.

REDACTED

REDACTED

118. Reginault was directly involved in matters relating to the prosecution of the Stamm Patents.

REDACTED

120. Reginault submitted a declaration during the prosecution of Application 09/899,016, discussed further below, and Application 10/288,425, which became the '881 Patent. The duty of disclosure also attaches to this declaration. The declaration is per se material.

121. The Reginault Declaration expressly recites that the prosecution claims stood rejected over Curtet. "I am a co-inventor of U.S. Patent No. 4,895,726 (the Curtet reference), which has been cited by the U.S. Patent Office to reject the claims. . . ."

122. The Reginault Declaration submits dissolution data of Lipanthyl® 200M 250 contains 250 mg of fenofibrate, and is manufactured in accordance with the Boyer patent (U.S. Patent No 4,800,079) and marketed by Fournier.

123. The Boyer patent describes a product having controlled release of fenofibrate, as opposed to a product for immediate release of fenofibrate.

124. Reginault supervised the dissolution tests of Lipanthyl® 200M f250, the results of which are reported in his declaration.

125. The Lipanthy® 200M 250 capsule contents, not the entire intact capsule, was used as the test sample.

REDACTED

127. Reginault was Fournier's technical point of contact for Abbott.

128. Reginault was aware of the duty to disclose material information when providing submissions to the PTO during the prosecution of a patent application. He signed a declaration and power of attorney in connection with the application that led to Curtet on January 11, 1989. The declaration includes an express acknowledgement of the duty of disclosure: "I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, § 1.56(a)."

129. Paragraph 4 of the Reginault Declaration recites: "I am a co-inventor of U.S. Patent 4,8956,726 (the Curtet reference), which has been cited by the U.S. Patent Office to reject the claims in the above-identified application." The "above-identified" applications include the application that led to the '881 patent and Application Ser. No. 09/899,026.

130. Paragraph 5 of the Reginault Declaration recites: "I have read and understood PCT/IB98/00065, and the U.S. Application Nos. 09/899,026 and 10/288,415" (i.e., the above-identified application). U.S. Application No. 10/288,425 is the application that led to the '881 patent in suit. Prosecution claim 1 of this application recites a dissolution profile, and issued as claim 1 of the '881 patent. The applications also include Figure 1, which compares the dissolution profiles of an embodiment of Curtet and the alleged invention.

131. The Reginault Declaration submitted dissolution data for Lipanthyl® 200M 250 and fenofibrate tablets to overcome an obviousness rejection over U.S. Patent No. 4,800,079 (Boyer) in view of Curtet.

132. Reginault knew that the prosecution claims (claims 1-14 and 22-41) of the '881 patent were rejected over Curtet Ex. 13, ¶ 4. On information and belief, Reginault also knew that the claims of the applications that led to the other Stamm Patents had also been rejected over Curtet.

133. The February 26, 2003 Office Action during the prosecution of the '881 patent, rejected the claims as obvious over Curtet alone or in view of U.S. Patent No. 6,042,847 (*Kerc et al.*), and as obvious over Boyer in view of Curtet.

134. Reginault conducted tests and submitted results to overcome the rejection over Boyer in view of Curtet. However, Reginault never disclosed the better dissolution results for the Curtet product known to Reginault and Fournier.

REDACTED

138. Some of the non-disclosed data met claim elements of each of the Stamm Patents that were not met by the data disclosed to the PTO.

139. At the time that Reginault filed his Declaration, the claims that were being prosecuted were not limited to any particular dosage. Moreover, the specifications of the Stamm Patents do not limit the invention to a particular dosage.

REDACTED

140. In addition to better dissolution test results, Reginault failed to disclose problems that may have caused the dissolution results for the capsule embodiments of the prior art reported in the Stamm Patents to be lower than he knew they should be, based upon data obtained by Fournier.

REDACTED

142. The Patent and Trademark Office had no way of knowing this unfavorable information.

143. Without disclosure of the withheld data, the declaration was misleading.

144. The information that was not disclosed during the prosecution of the Stamm Patents was highly material to the patentability of the claims under examination. By presenting bad dissolution data while withholding good dissolution data with respect to the prior art, Fournier misled the PTO about the degree of improvements over the prior art (if any) offered by the Stamm formulation. This violated Fournier's duty of disclosure.

145. The data withheld by Fournier was highly material both in view of (1) the original argument for patentability over Curtet based on the reportedly improved dissolution profiles that were presented in the specification and its examples in each of the four Stamm Patents, and (2) the further arguments Fournier made during prosecution to overcome rejections based on prior art including Curtet.

146. The material information was withheld and the misleading declaration was submitted with an intent to deceive the Patent and Trademark Office.

147. Therefore, each of the Stamm Patents is unenforceable.

148. Reginault's conduct during the prosecution of each of the Stamm Patents caries with it a taint that extends to all related applications.

149. Fournier's withholding of material information with an intent to deceive the Patent and Trademark Office during the prosecution of the applications that issued as the Stamm Patents soiled Fournier's hands so as to render all of the Stamm Patents unenforceable.

150. The four Stamm Patents are closely related. The written description of the invention is identified in each; only the claims differ. Each assets patentability based on a purported significant improvement over the period art with respect to the dissolution of fenofibrate oral formulations for human use. The new formulation process they assert is common to all four. The specifications of each of the four Stamm Patents assert this position

based on comparisons with the same purported dissolution figures for prior art fenofibrate formulations. In the case of each patent, highly material prior art that showed better dissolution performance for prior art formulations was withheld from the PTO. The same misleading comparison was the prior art was thus put forward with respect to each patent.

151. Moreover, Fournier's purpose in withholding the information, and the overall purpose of obtaining the Stamm Patents, was the same in the case of each patent: to prohibit or delay generic competition for fenofibrate products. Fournier's repeated failure to disclose highly material information in each case was part of Fournier's and Abbott's single, overall coordinated scheme.

152. The misrepresentations in the case of each of the Stamm Patents thus bear an immediate and necessary relation to the patent applications for all four of the Stamm Patents, and to the allowance of all of them. Accordingly, if any of the Stamm Patents is unenforceable as a result of Fournier's intentional failure to disclose highly material information concerning the prior art, all four of the Stamm Patents are similarly unenforceable.

153. On or about February 23, 2005, after Teva raised the issue of Fournier's inequitable conduct in an affirmative defense in the Tablet Lawsuits, Fournier filed certain Information Disclosure Statements ("IDSs") with PTO in conjunction with two then-pending applications from the Stamm family of patents 00 U.S. Patent Application Nos. 09/899,026 ("the '026 Application") and 10/290,333 ("the '333 Application"). These applications directly descent from the original application which also gave rise to the four Stamm Patents-in-suit. The IDSs Fournier filed in connection with these later applications included documents containing the 1997 dissolution test data from the 2177 batch that Fournier had previously withheld from the PTO.

154. By filing these IDSs in connection with the prosecution of the ‘026 Application and the ‘333 Application, Fournier effectively conceded the materiality to the Stamm Patents of the previously withheld 1997 dissolution test data.

155. After Fournier filed the IDSs, the Examiner rejected the ‘026 Application and the ‘333 Application. In response to those rejections, Fournier was required to, and did, substantially revise the dissolution profiles of the compositions it was claiming in those applications, making them substantially different from the dissolution profiles set out in claims of the Stamm Patents-in-suit. The Examiner allowed the ’026 Application and the ‘333 Application only after those substantial changes to the claimed dissolution profiles were made.

156. The Examiner’s rejection of the ‘026 Application after becoming aware of the 1997 dissolution data that Fournier had previously withheld, and the subsequent allowance of those applications only after the dissolution profiles were substantially changed, further demonstrates the materiality of the previously withheld dissolution test data to the Stamm Patents.

WRONGFUL PATENT LISTING IN THE ORANGE BOOK

157. A patent is listable in the Orange Book only if the patent “claims the drug . . . or a method of using such drug” and the patent is one “with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug.” 21 U.S.C. §§ 355(b)(1). A patent that is unenforceable does not meet the criteria for listing in the Orange Book. Listing an unenforceable patent in the Orange Book is wrongful, improper, and an abuse of the Hatch-Waxman regulatory scheme.

158. Listing a patent in the Orange Book that is not properly listable can have significant anticompetitive consequences. As the United States Federal Trade Commission has stated, "the Orange Book listing scheme is susceptible to opportunistic behavior. The NDA holder can exploit the listing scheme by obtaining patents and listing them in the Orange Book in block FDA approvals of generic rivals for 30 months, even when the NDA holder does not reasonably expect the patents to ultimately hold up in court." *See* Analysis to Aid Public Comment in the Matter of Bristol-Myers Squibb Company, File Nos. 001 0221, 011 0046, and 021 0181.

159. The listing of a patent in the Orange Book is a private act undertaken by the NDA holder, which submits the patent to the FDA for listing in the Orange. Book. The FDA acts in a purely ministerial matter, receiving the submission for the NDA holder and including that submission in the Orange Book. FDA does not analyze the validity or enforceability of the patent at issue, and FDA does not analyze whether the patent is appropriately listable to the NDA at issue. Listing a patent in the Orange Book does not involve petitioning activity.

160. Fournier's inequitable conduct in the PTO, as alleged above, rendered all the Stamm Patents unenforceable, as Abbott and Fournier knew. As a result, Abbott and Fournier had no basis to list any of the Stamm Patents in the Orange Book.

161. Abbott listed the '670 Patent, the '405 Patent, and '552 Patent, and the '881 Patent in the Orange Book in furtherance of Abbott's and Fournier's overall scheme to monopolize. Abbott's listing of those patents is wrongful and actionable, both as one step in the overall scheme and standing alone.

162. At the times Abbott listed the various Stamm Patent in the Orange Book, a claim that Teva's Tablet ANDA (or any other ANDA) infringed any of the Stamm Patents could not reasonably be asserted, due to the unenforceability of those patents.

163. At the times Abbott listed the Stamm Patents in the Orange Book and thereafter, Abbott and Fournier did not reasonably believe and could not have reasonably believed that they could reasonably assert a claim of patent infringement concerning any of the Stamm Patents against Teva, due to the unenforceability of those patents.

164. At the times Abbott listed the Stamm Patents in the Orange Book and thereafter, the Stamm Patents were not listable in the Orange Book, and Abbott and Fournier did not reasonably believe and could not have reasonably believed that the Stamm Patents were listable in the Orange Book.

165. Despite knowing that the Stamm Patents were unenforceable and therefore not listable in the Orange Book, Abbott listed the Stamm Patents in the Orange Book.

166. Abbott and Fournier knew that by listing the '670 Patent in the Orange Book, they would be able to obtain an automatic 30-month stay preventing FDA approval of any ANDA application seeking approval for original-formulation fenofibrate tables, including the Tablet ANDA subsequently filed by Teva.

167. Abbott and Fournier knew that by listing the '405 Patent in the Orange Book, they would be able to obtain an automatic 30-month stay preventing FDA approval of any ANDA application seeking approval for original-formulation fenofibrate tablets, including the Tablet ANDA subsequently filed by Teva.

168. As a result of Abbott's listing of the '670 Patent and the '405 Patent in the Orange Book, Teva was required to file Paragraph IV certifications to those patents with its Tablet ANDA.

169. But for Abbott's listing of the '670 Patent and the '405 Patent in the Orange Book, Teva would not have been required to file Paragraph IV certifications as to those patents in connection with its Tablet ANDA.

170. Because Teva was required to and did file Paragraph IV certifications to the '670 Patent and the '405 Patent with its Tablet ANDA as a result of Abbott's listing of that patent in the Orange Book, Abbott and Fournier were able to implement an automatic 30-month stay of FDA approval of Teva's Tablet ANDA on the basis of those patents by filing a patent infringement suit based on the '670 Patent and the '405 Patent, C.A. No. 02-1512 (D. Del). The statutory expiration date for this stay (absent an earlier court decision) was March 2, 2005. Even though Abbott and Fournier also sued Teva on the '726 Patent, which also triggered a stay, Abbott and Fournier stopped prosecuting their claims under the '726 Patent by no later than March 20, 2003. But for Abbott's and Fournier's listing of the '670 Patent and the '405 Patent in the Orange Book, the original stay of Teva's Tablet ANDA would have been lifted no later than March 20, 2003.

171. Abbott and Fournier's conduct in listing the '670 Patent and the '405 Patent in the Orange Book was unreasonable, wrongful, exclusionary, abusive, unreasonably anticompetitive, objectively baseless, and intended to interfere with Teva's ability to launch sales of its generic fenofibrate tablets.

172. Abbott and Fournier knew that by listing the '552 Patent in the Orange Book, they would be able to obtain a second, successive 30-month stay that would further delay FDA approval of Teva's Tablet ANDA.

173. Once Abbott listed the '552 Patent in the Orange Book to its NDA for original formulation TriCor® tablets, Teva was required to amend its ANDA to file a certification as to the '551 Patent. As a result, Teva filed a Paragraph IV certification to the '552 Patent on July 29, 2003.

174. But for Abbott's listing of the '552 Patent in the Orange Book, Teva would not have been required to file, and would not have filed, a Paragraph IV certification to the '552 Patent in connection with Teva's Tablet ANDA.

175. Because Teva was required to and did file a Paragraph IV certification to the '552 Patent with its Tablet ANDA as a result of Abbott's listing of that patent in the Orange Book, Abbott and Fournier were able to implement a second, successive automatic 30-month stay of FDA approval of Teva's Tablet ANDA by filing a patent infringement suit based on the '552 Patent, C.A. No. 03-847 (D. Del.). The statutory expiration date for this second stay (absent an earlier court decision) was February 2, 2006, approximately one year later than the statutory expiration date for the original stay. But for Abbott's improper listing of the '552 Patent in the Orange Book, Abbott and Fournier could not have implemented or maintained a successive 30-month stay by suing Teva under Hatch-Waxman for alleged infringement of the '552 Patent.

176. Abbott's and Fournier's conduct in listing '552 Patent in the Orange Book was unreasonable, wrongful, exclusionary, abusive, unreasonably anticompetitive, objectively baseless, and intended to interfere with Teva's ability to launch sales of its generic fenofibrate tablets.

177. But for Abbott's and Fournier's wrongful conduct in listing the '552 Patent in the Orange Book, FDA would have granted final approval rather than tentative approval to Teva's Tablet ANDA by no later than March 2, 2005, when the initial stay period expired.

178. But for Abbott's and Fournier's wrongful conduct in listing the '670 Patent, the '405 Patent, and the '552 Patent in the Orange Book, FDA would have granted final approval rather than tentative approval to Teva's Tablet ANDA in March of 2004.

179. But for Abbott's listing of all the Stamm Patents in the Orange Book, there would have been no subject matter jurisdiction for an infringement action by Abbott and Fournier against Teva concerning the Stamm Patents under Section 271(e)(2). Therefore, Abbott and Fournier could not have filed or maintained the Tablet lawsuits concerning the Stamm Patents.

COUNT I: VIOLATIONS OF SECTION 2 OF THE SHERMAN ANTITRUST ACT: REQUEST FOR INJUNCTIVE RELIEF

180. Plaintiff incorporates by reference the preceding allegations.

181. Defendants knowingly and willfully engaged in a course of conduct designed to unlawfully extend their monopoly power. This course of conduct included filing and prosecuting baseless patent infringement actions against companies seeking to market generic fenofibrate products; obtaining additional patents (including the Stamm Patents) and listing those patents in the Orange Book, even as Defendants knew that the Stamm Patents were unenforceable; de-listing reference codes in the NDDF; and using their market power to intentionally shift the fenofibrate market from dosages and/or formulations in which Defendants confronted generic competition to dosages and formulations in which they did not. Each of these actions is independently actionable as a violation of the antitrust laws; each is also actionable as a component in an overall scheme to monopolize. Defendants' scheme was designed to delay the

introduction of generic formulations of TriCor® into the market and was in violation of Section 2 of the Sherman Act.

182. Defendants possessed monopoly power in the relevant market. Defendants intentionally and wrongfully maintained their monopoly power in the relevant market in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2. While obtaining and possessing their unlawful monopoly power over the market for fenofibrate drugs, Defendants set and maintained the price of TriCor® at artificially and/or supra-competitive levels.

183. Plaintiff has been injured in its business or property by reason of Defendants' antitrust violations. Its injury consists of having paid and continuing to pay higher prices for fenofibrate products than it would have paid in the absence of those violations. Such injury is of the type antitrust laws were designed to prevent and flows from that which makes Defendants' conduct unlawful. Plaintiff continues to purchase fenofibrate drug products and is likely to continue to do so in the future. Injunctive relief is, therefore, appropriate under 15 U.S.C. § 26.

184. Plaintiff seeks to enjoin Defendants from engaging in future anticompetitive practices concerning the manufacture, distribution or sale of TriCor®. Plaintiff does not seek damages under the federal antitrust laws.

COUNT II: VIOLATIONS OF STATE ANTITRUST LAWS

185. Plaintiff incorporates by reference the preceding allegations.

186. As described above, Defendants knowingly and willfully engaged in a course of conduct designed to unlawfully extend their monopoly power. This course of conduct included filing and prosecuting baseless patent infringement actions against companies seeking to market generic fenofibrate products; obtaining additional patents (including the Stamm Patents) and listing those patents in the Orange Book, even as Defendants knew that the Stamm Patents were

unenforceable; de-listing reference codes in the NDDF; and using their market power to intentionally shift the fenofibrate market from dosages and/or formulations in which Defendants confronted generic competition to dosages and formulations in which they did not. Each of these actions is independently actionable as a violation of the antitrust laws; each is also actionable as a component in an overall scheme to monopolize. Defendants' scheme was designed to delay the introduction of generic formulations of TriCor® into the market and was in violation of Section 2 of the Sherman Act.

187. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant markets in violation of Arizona Revised Stat. § § 44-1401, et seq., with respect to purchases of TriCor® in Arizona by Plaintiff.

188. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant markets in violation of Cal. Bus. & Prof. code § § 16700, et seq., and Cal. Bus. & Prof. Code § § 17200, et seq., with respect to purchases of TriCor® in California by Plaintiff.

189. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant markets in violation of Nev. Rev. Stat. Ann. § 598A., et seq., with respect to purchases of TriCor® in Nevada by Plaintiff.

190. Plaintiff has been injured in its business or property by reason of Defendants' antitrust violations alleged in this Count. The injury consists of paying higher prices for fenofibrate prescription drugs than Plaintiff would have paid in the absence of those violations. This injury is of the type the antitrust and consumer protection laws of the above States were designed to prevent and flows from that which makes Defendants' conduct unlawful.

COUNT III: VIOLATIONS OF STATE CONSUMER FRAUD AND UNJUST ENRICHMENT LAWS

191. Plaintiff incorporates by reference the preceding allegations.

192. Defendants engaged in unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of the state consumer protection statutes listed below by improperly filing and prosecuting baseless patent infringement actions against companies seeking to market generic fenofibrate products; obtaining additional patents (including the Stamm Patents) and listing those patents in the Orange Book, even as Defendants knew that the Stamm Patents were unenforceable; de-listing reference codes in the NDDF; and using their market power to intentionally shift the fenofibrate market from dosages and/or formulations in which Defendants confronted generic competition to dosages and formulations in which they did not. As a direct and proximate result of Defendants' anticompetitive, deceptive, unfair, unconscionable, and fraudulent conduct, Plaintiff was deprived of the opportunity to purchase a generic version of TriCor® and was forced to pay higher prices for fenofibrate.

193. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ariz. Rev. Stat. § 44-1522, et. seq.

194. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Cal. Bus. & Prof. Code § 17200, et. seq.

195. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Colo. Rev. Stat. § 6-1-105, et. seq.

196. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Nev. Rev. Stat. § 598.0903, et. seq.

197. Defendants have engaged in unfair competition or unfair or deceptive acts or practices or made false representations in violation of Okla. Stat. tit. 15 § 751, et. seq.

198. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Or. Rev. Stat. § 646.605, et. seq.

199. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tex. Bus. & Com. Code § 17.41, et. seq.

200. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wash. Rev. Code. § 19.86.010, et. seq.

201. Plaintiff has been injured in its business and property by reason of Defendants' anticompetitive, unfair or deceptive acts alleged above. Plaintiff's injury consists of paying higher prices for TriCor® prescription drugs than it would have paid in the absence of these violations. This injury is of the type the state consumer protection statutes were designed to prevent and directly results from Defendants' unlawful conduct.

202. Defendants have benefited from the monopoly on their sales of TriCor® resulting from the unlawful and inequitable acts alleged in this Complaint.

203. Defendants' financial benefits resulting from their unlawful and inequitable conduct are traceable to overpayments for TriCor® by Plaintiff.

204. Plaintiff has conferred upon Defendants an economic benefit, in the nature of profits resulting from unlawful overcharges and monopoly profits, to the economic detriment of Plaintiff.

205. The economic benefit of overcharges and unlawful monopoly profits derived by Defendants through charging supra-competitive and artificially inflated prices for TriCor® is a direct and proximate result of Defendants' unlawful practices.

206. The financial benefits derived by Defendants rightfully belong to Plaintiff, as Plaintiff paid anticompetitive and monopolistic prices, inuring to the benefit of Defendants.

207. It would be inequitable for the Defendants to be permitted to retain any of the overcharges for TriCor® derived from Defendants' unfair and unconscionable methods, acts and trade practices alleged in this Complaint.

208. Defendants should be compelled to disgorge for the benefit of Plaintiff all unlawful or inequitable proceeds received by them.

209. A constructive trust should be imposed upon all unlawful or inequitable sums received by Defendants.

PRAYER

WHEREFORE, Plaintiff respectfully requests that this Court enter an Order:

A. declaring Defendants' conduct to be in violation of § 2 of the Sherman Antitrust Act;

B. enjoining and restraining Defendants' continuing violations of § 2 of the Sherman Antitrust Act;

C. declaring Defendants' conduct to be in violation of the antitrust, deceptive practices, and consumer fraud statutes of the states listed above;

D. granting Plaintiff equitable relief in the nature of disgorgement, restitution, and the creation of a constructive trust to remedy Defendants' unjust enrichment;

E. granting Plaintiff damages as permitted by law;

F. granting Plaintiff the cost of prosecuting this action, together with interest and reasonable attorney fees, and costs;

G. granting other relief as this Court may deem just and proper.

JURY TRIAL DEMAND

Plaintiff demands a trial by jury of all issues so triable.

DATED: October 4, 2005

Respectfully submitted,

MURPHY SPADARO & LANDON

/s/ Jonathan L. Parshall___
Jonathan L. Parshall (#3247)
1011 Centre Road, Suite 210
Wilmington, Delaware 19805
Telephone: 302-472-8100
Telecopy: 302-472-8135

William Christopher Carmody
John W. Turner
Shawn J. Rabin
SUSMAN GODFREY L.L.P.
901 Main Street, Suite 4100
Dallas, Texas 75202
Telephone: 214-754-1900
Telecopy: 214-754-1933

Mark D. Fischer
Mark S. Sandmann
Jeffrey C. Swann
RAWLINGS & ASSOCIATES
325 West Main, Suite 1700
Louisville, Kentucky 40202
Telephone: 502-587-1279
Telecopy: 502-584-8580

Kendall Zylstra
SCHIFFRIN & BARROWAY, L.L.P.
280 King of Prussia Road
Radnor, PA 19087
Telephone: 610-822-0276
Telecopy: 610-667-7056

ATTORNEYS FOR PLAINTIFFS

CERTIFICATE OF SERVICE

I, Jonathan L. Parshall, do hereby certify that on the 4th day of October, 2005, I electronically filed Plaintiff's First Amended Complaint (Public Version), using CM/ECF, which will send notification of such filing to all registered participants.

/s/ Jonathan L. Parshall____
Jonathan L. Parshall (#3247)